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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/570,133

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Kazunari Ushida

2006-0286A

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08/12/2009

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EXAMINER

ROGERS, JAMES WILLIAM

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

08/12/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/570,133 | Applicant(s) USHIDA ET AL. | |
| | Examiner JAMES W. ROGERS | Art Unit 1618 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38-63 is/are pending in the application.
- 4a) Of the above claim(s) 48,49 and 52-63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38-47,50 and 51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>03/01/2006, 06/12/2006 and 03/12/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Claims 48-49 and 52-63 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention or species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 06/12/2009.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 47 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically it is unclear how an element such as selenium, cobalt, manganese, zinc or copper could in any way be construed to mean a microorganism, which generally refers to any organism (life form) that is microscopic in size.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 38-43,45-46 and 50-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Peoples et al. (US 6,207,217 B1, cited by applicants in international search report).

Peoples teaches an animal nutrition composition that contains metabolizable poly-3-hydroxyalkanoates (PHA) including homopolymers and copolymers of polyhydroxybutyrate (PHB). See abstract, col 3 lin 16-40 and claims. The PHA's could be produced by microorganisms selected from transgenic crops or bacteria species, plant species that produce an overabundance of PHB could be fed to the animals directly. See col 1 lin 45-56, col 3 lin 61-col 4 lin 31. Regarding the limitation within claim 38 that the β -hydroxy short-medium fatty acid is delivered to the large intestine, the examiner treated this as a mechanism that inherently occurs upon oral administration of the claimed β -hydroxy short-medium fatty acid polymer to an animal, since the polymer of Peoples is the same and the composition that contains the polymer is a foodstuff that would be consumed orally the examiner considers this limitation inherently met.

Claims 38-45 and 50-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Yalpani (US 5,229,158).

Yalpani teaches PHA homopolymers and copolymers, preferably PHB which are useful as substitutes for fats in various food products. See abstract, col 1 lin 6-10 and claims. The limitation within claim 38 that the β -hydroxy short-medium fatty acid is delivered to the large intestine is treated as in the Peoples rejection above, that is since the PHA is the same and delivered orally it will inherently be delivered to the large intestine. Regarding claim 44, the repeat units for PHA taught in Peoples is anywhere

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from 500-17,000, PHB with 500 repeat units has a MW ~43,000 Da and PHB with 17,000 repeat units has a MW ~1,462,000 Da, both endpoints are within applicants claimed range. (PHB repeat unit is $C_4H_6O_2$, the MW of each unit is ~86 Da).

Claims 1-39,41-45,47 and 50-51 are rejected under 35 U.S.C. 102(b) as being rejected by Ibay et al. (US 5,206,341).

Ibay teaches PHA copolymers, including PHB copolymers that can be used as binders in sustained release dosage forms and cereals or as a coating for drugs. See abstract, col 7 lin 19-28 and claims. The limitation within claim 38 that the β -hydroxy short-medium fatty acid is delivered to the large intestine is treated as in the Peoples rejection above, that is since the PHA is the same and delivered orally it will inherently be delivered to the large intestine. Regarding claim 44, Peoples teaches that the polymers generally have a MW from about 2,000 to about 10,000. See col 5 lin 51-54. Regarding claim 47, Ibay claims the use of a metallic substances such as zinc in combination with the PHA copolymers.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618